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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,676	09/19/2005	Osamu Cynshi	CYNSHI6	8449

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EXAMINER	
PETERSEN, CLARK D	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/549,676	CYNSHI ET AL.	
	Examiner	Art Unit	
	Clark D. Petersen	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Abstract Objection

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it includes legal terminology such as “said”. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Lynch et al (J Clin Invest, 1994). Lynch et al teach a method of isolating biological samples of either plasma or purified low density lipoprotein (LDL) from human volunteers (see Methods, p. 999, col. 2, for example). LDL isolated in the manner of Lynch et al (i.e. ultracentrifugation; see p. 999, col. 1) inherently contains lipophilic antioxidants such as α-tocopherol (see Vieira et al, J Lipid Res, 1996; see Introduction and Discussion, for example). Lynch et al add a free radical generator to the isolated LDL to initiate an oxidation reaction (see Methods, p. 999, col. 1, for example). They stop their reactions by placing them on ice, and subsequently analyze the reactions for oxidation products (see Methods, p. 999, col. 1, for example). In particular the method they teach uses 2,2'-azobis amidinopropane hydrochloride (AAPH) as the free radical generator, and that this is applied to LDL in particular at a concentration of 10 mM. Lynch et al then isolated oxidized cholesterol variants and measure their quantity by HPLC (see Methods, p. 999, col. 2, for example).

Therefore the teachings of Lynch et al are deemed to anticipate the instant claims 1-11.

Claims 1, 3, 4, and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Zarev et al (FEBS Lett, 1999). Zarev et al teach a method of isolating LDL by ultracentrifugation from human donors, which, as discussed above regarding Vieira et al, inherently contains antioxidants such as α-tocopherol. They teach a method of oxidizing LDL by addition of copper (see p. 104, col. 1, for example). The reaction is stopped by addition of EDTA (see p.104, col. 1, for example). Various cholesterol esters and other cholesterol-oxidation products were isolated and characterized by detection in a HPLC machine at 205 nm (ultraviolet wavelength) (see p. 104, col. 2, for example).

Therefore the teachings of Zarev et al are deemed to anticipate the instant claims 1, 3, 4, and 8-12.

Claims 1-6, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Crawford et al (Diabetes, 1999). Crawford et al teach an assay for evaluating antioxidant efficacy. Specifically they administer an antioxidant called troglitazone to human patients Plasma was removed from the patients, and LDL was purified from the plasma, or alternatively, intact plasma was used (see p. 785, col. 2, for example); as discussed above, LDL and plasma inherently contain α-tocopherol. The free radical generator AAPH was added to the whole plasma in particular, and generation of oxidation products was measured continuously in a spectrophotometer (see p. 785, col. 2, for example). A portion of the study tested the efficacy of troglitazone as an

antioxidant that could protect LDL. As discussed above, Crawford et al isolated LDL and incubated it with troglitazone, or, alternatively, isolated human plasma and incubated it with troglitazone. In either case, LDL was re-isolated by ultracentrifugation and the impact of incubation with troglitazone on its oxidative vulnerability was measured (see p. 784, col. 2, for example). As a positive control, to ensure some degree of prevention of oxidation of isolated LDL, the drug probucol (a lipophilic molecule known to interact well with LDL) was added to some LDL samples, reading on claim 18 (see p. 785, col. 2, for example).

Therefore the teachings of Crawford et al are deemed to anticipate the instant claims 1-6, 17, and 18.

Claims 1-7 and 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Aldini et al (US Pat Pub # 2002/0182736 A1, published Dec. 5, 2002). Aldini et al teach a method of evaluating the antioxidant potential of a biological sample. They teach that one can remove a sample and add a lipophilic or hydrophilic radical generator to it (see p. 1, paras [0009] and [0010], for example). They quantitate the oxidation of a fluorescent liphophilic dye, reading on quantitating oxidation products (see para [0010], for example). These measurements are taken at multiple time points during the course of the experiment (see Example 4, p. 14, col. 2, for example). In particular Aldini et al teach that the biological sample can be blood, plasma or serum (see p. 1, para [0011], for example). Blood components inherently contain α-tocopherol, which is an antioxidant (see p. 2, para [0018], for example). Aldini et al teach that one can test the oxidative buffering capacity of a blood product by adding the

free radical generator 2,2'-azobis amidinopropane hydrochloride, and that this can be administered in concentrations of 10-20 mM (see p. 12, para [0134], for example), so as to allow for a continuous reaction that can be measured at multiple time points. Additionally, Aldini et al teach that α-tocopherol can be added exogenously to a lipid compartment of a sample removed from a patient, to boost the inherent antioxidative properties of the α-tocopherol already in the sample (see, p. 3, para [0022], for example). Lastly, Aldini et al teach that their method is useful for diagnosing a free radical disorder (see p. 2, para [0018], for example), the term free radical disorder encompassing diseases such as hemhorrage, autoimmune disease, Alzheimer's, and neoplasia, among others (see p. 6, para [0068], for example).

Therefore the teachings of Aldini et al are deemed to anticipate the instant claims 1-7 and 13-16.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clark D. Petersen whose telephone number is (571)272-5358. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571)272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CDP
8/2/2006

CHRISTOPHER R. TATE
PRIMARY EXAMINER